said upper surface of said sections being directly exposed for direct engagement with the foot of the user or a sock or stocking on the foot of the user.

46. Footgear with pressure relief areas for the foot as defined in claim 45 wherein said inner sole includes an underlying flexible sheet to which said sections are removably secured; and said sections being secured to said sheet, and said inner sole being secured into said shoe by hook and loop type fastening arrangements.

47. Footgear with pressure relief areas for the foot as defined in claim 45 wherein said sections are softer and more resilient adjacent said upper surface as compared with the lower portion of said sections adjacent said lower surfaces.

REMARKS

The claims which are active in this application are original claims 1-23, claims 33-38 previously presented, and claims 39-47 presented with this Request for Continuing Examination.

Initially, attention is directed to the Supplemental Declaration of Tracy Grim, one of the inventors in the present case. This Declaration is the result of extended conversations with the inventors in this case.

Before going into specifics, however, it may be useful to mention some background on foot ulcers for diabetic patients. Such ulcers present a very serious problems for the patient, because, if they do not heal they may become progressively worse, and in many cases amputation of the foot or lower leg has been necessary. Many doctors have prescribed bed rest for several weeks or a month or two, so that the patient will stay off their feet, giving the ulcers a chance to heal.

The present invention with fully selectable areas where pressure relief may be achieved, has been a break through in the handling of this serious problem; and patients provided with this new product have been able to continue to pursue their normal daily activities without being confined to bed-rest.

Now, the Andrews patent is directed to this type of problem but has serious shortcomings. Both in this amendment and in the Declaration, we are directing attention to these shortcomings of the Andrews structure.

Andrews shows an insole having several spaced depressions, and removable inserts which are in fixed locations.

In the recent Office Action a certain passage from the Andrews patient has been quoted, as follows:

> "the number, shape and position of the depressions 18 and 18a may be chosen as best suited to the needs of most users".

However, it is respectfully noted that this passage clearly indicates that there will be a number of depressions; and accordingly there will necessarily be ridges or raised areas between the depressions.

Accordingly Andrews definitely does not disclose a full array of removable inserts, but only specific, selected areas where there are depressions and inserts.

We now ask that the Patent Office consider the practical problems which would arise in the use of the Andrews device, as set forth in the Attached Supplemental Declaration and repeated here:

(a) First, the Andrews insole is manufactured with depressions in selected areas, and necessarily has ridges or raised areas between the depressions, as follows:

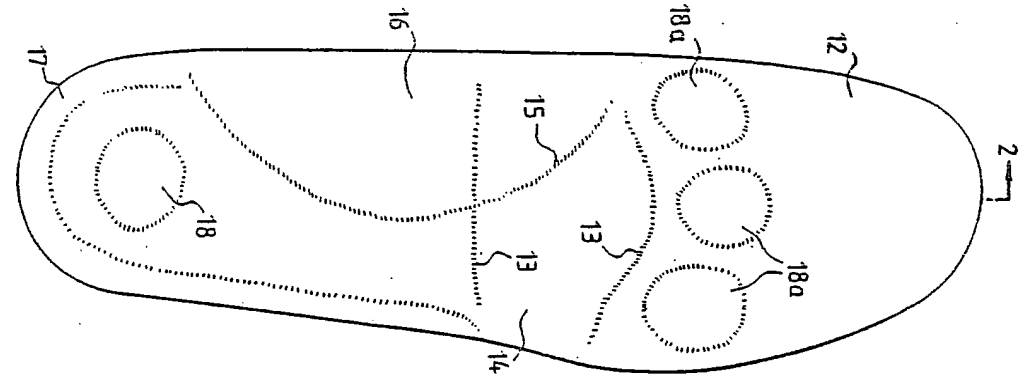


FIG. 1.

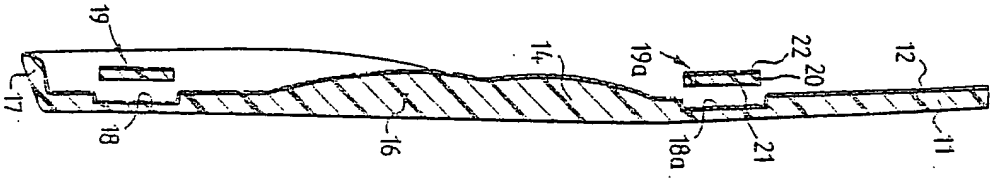
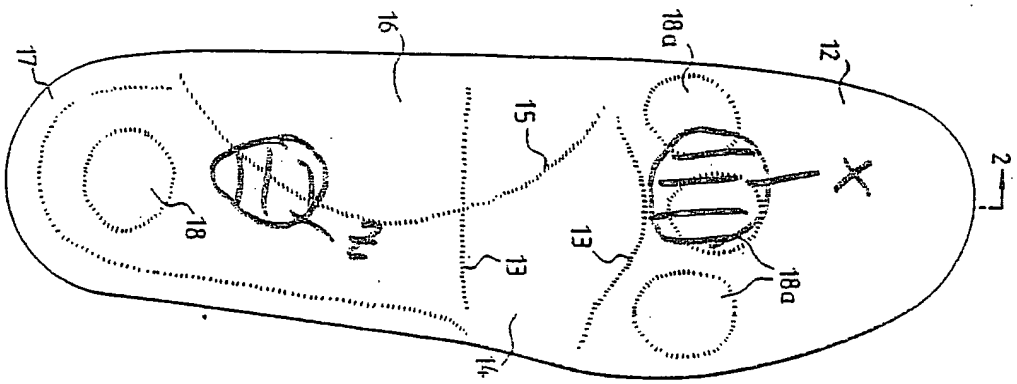


FIG. 2.

(b) The basic Andrews construction might initially relieve pressure on at least one of the areas contemplated by Andrews. However, now consider the case where the same patient has the ulcer enlarged to extend over the area indicated at "X" below, or has a new ulcer develop at area "Z", shown below (which is common to diabetic patients having advanced bony deformation, called a "Charcot joint"):



What will the patient or his or her doctor do? Will they order a new specially made insole from the manufacturer? Or will they try to cut the existing insole to the new configuration? This dilemma clearly points up the shortcomings of the Andrews product.

As noted above, the Andrews patent states that the number and position of depressions may be chosen as best suited to the needs of most patients. In accordance with this statement, the Andrews as manufactured will have depressions and will have intermediate raised portions. Accordingly, when the ulcerated areas underlie the raised portions, the patient and his or her doctor cannot readily handle the situation. The intermediate raised portions can start new ulcers because of focal pressure points.

This is the basic problem with the Andrews patent and product. It lacks flexibility and practicality. It is believed that the foregoing analysis indicates why the Andrews product is not seen on the market, while the assignee of the present invention has had nearly $6,000,000 in sales in the last four years and two months.

It is recognized that the foregoing diagramatic analysis, in combination with the Declaration, is somewhat repetitious; but the Patent Office has seemed to ignore our previous analyses and arguments relative to the Andrews patent, and we therefore specifically request that a recognition of the serious short-comings of the Andrews patent be included in any further response by the Patent Office to this amendment.

We believe that the claims now presented in this application represent significant "Progress in the useful arts", to the Constitutional phrases See Art. 1, Sec. 8, Cl.8, of the U.S. Constitution), and should not be summarily disversed on the basis of the impractical Andrews structure, and an ill-fitting proposed combination of references.

Now, concerning the amendments to claims 35, and 37, claim 35 has been amended to refer back to claim 33, and the word "footgear" has been substituted for "shoe". The structure defined in claim 35 is shown in Figs. 2 and 6 of the patent application drawings. Regarding the amendment to claim 37, they involved the addition to the claim preamble of "with pressure relief areas for the foot, said pad having a sole area extending for substantially the entire area underlying the foot of a user". This structure is shown in Fig. 2 of the drawings, at reference numerals 68, 70 and 72, for example. This figure of the drawings also provides support for most of the other limitations included in claims 33 – 47. The matter of varying resiliency of the sections is mentioned in col. 3 of the patent at item No. 3 in the list toward the bottom of the column. The matter of "no compression set" is disclosed in col. 8, line 34 et seq. The footgear "flaps" are shown at 48 and 50 in Fig. 2 of the drawings.

Referring now to the proposed combination of references, the Andrews and Kellerman patents, it is initially noted that the Kellerman device is not directed to relief of ulcers on the feet but to problems involving heel spurs or bunions, see Kellerman, col. 3, lines 37 and 38. Kellerman's structure involves a low friction insert with a top layer of ultra-high molecular weight polyethylene which is a very stiff material.

Continuing with the analysis, if this surface layer of Kellerman were to be used as the surface layer of Andrews, when the inserts were removed, the foot would slide around some on the low friction layer, and the stiff edges of this upper layer would exacerbate the ulcer, and prevent healing. Because of the very fragile nature of the new skin grown in the ulcer healing process, as developed in detail in the attached Declaration, using the teachings of Kellerman to provide a low friction layer in the Andrews device would be disastrous for foot ulcers.

It is further noted that the Kellerman patent does not disclose the provision of non-contact relief as set forth in the claims present in this application, but instead provides a slippery full engagement upper layer on the insole, thus preventing ulcer healing.

Also, if the concept of lower areas of relief as suggested by Kellerman were applied to the Andrews patent, the upper portion of the Andrews structure would be in full engagement with the foot, thus preventing ulcer healing.

Section 103 of the patent act requires that obviousness be judged based on a person having ordinary skill in the art to which the subject matter pertains. In the present case, those skilled in the art would recognize that the problem faced by applicant, i.e., healing of foot ulcers, is quite distinct from the problem involving bone spurs and bunions. Foot ulcers require full surface relief for proper healing, while Kellerman teaches that a low friction surface in engagement with the foot, together with remote pressure relief is advantageous for accommodating bone spurs and bunions. Accordingly, those skilled in the art would not look to the Kellerman patent relative to teachings for handling foot ulcer healing.

In summary, it is only by following the teachings of this patent application that the proposed combination of references was proposed.

It is further noted that several new claims numbered 39 through 47 have been added by amendment. Considering claim 39, for example, it has a number of limitations not shown or suggested by the references. This includes the array of independent sections for directly engaging the foot, and a number of other limitations including the resilient sections having a height at least equal to their width. The nature and construction of the foot enclosing flaps is also set forth in this claim. All of these limitations are beyond anything shown in the prior art.

Dependent claim 40 further defines the construction of the footgear; and dependent claim 41 brings out the gradation in resiliency of the sections. While the Moronaga reference does disclose an insole with varying levels of resiliency, it is in the context of an athletic shoe, and there is no suggestions that it could be applicable in the resilient removable sections of a therapeutic shoe, where the softer upper surface has unique advantages in retaining the foot in position without sliding to promote ulcer healing.

The remaining new claims include various of the limitations discussed above in connection with claims 39-41, where these limitations are not present in the prior art.

THE REISSUE STATUTE

The Reissue Statute, 35 USC 251 specifically mentions and authorizes broadened reissues; and the present application was filed within the two year period specified in the statute for broadened reissues. Also of interest is the case law involving reissues as included, for example In re Willingham, 282 F.2d 353, 127 USPQ211 (CCPA 1960); In re Richamn 409 F.2d 269, 161 USPQ359, (CCPA 1969), and In re Wadlinger, 496 F.2d 1200, 181 USPQ826 (CCPA 1974).

In closing, the present invention represents a significant step forward, and constitutes significant "Progress in the useful arts". A number of years ago I was a Patent Examiner, and took pleasure in granting good patent protection on good inventions, and in assisting attorneys in obtaining these results, thereby rewarding applicants for the underlying R&D work and for the results of these efforts. In contrast, it has sometimes seemed to me that the prosecution of this case by the Patent Office has been on the basis that we should have a "non-patent system" instead of a constructive Pro-Patent System.

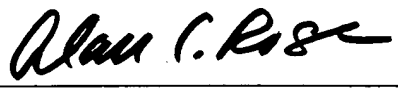
For completeness, we also request that the amendment and Declarations mailed to the Patent Office on October 9, 2001 be filed and accepted.

Concerning additional Supplemental Declarations, we note that the present claims have been discussed with the assignee and at least one of the inventors and they confirm that they will execute supplemental declarations. However, it is respectfully requested that this be deferred until claim language is finalized. Upon an indication that the claims are otherwise allowable, such declarations will be promptly supplied.

In the event that this patent application is not considered to be entirely in condition for allowance, it would be appreciated if the Examiner would grant a telephone interview. Applicant's attorney would prefer a personal interview with the Examiner, but is located in Los Angeles so that a personal interview is not practical. Accordingly, a comparable telephone interview would be appreciated if the application is not considered allowable. Thank you.

In conclusion, an early Notice of Allowance is solicited.

Respectfully submitted,



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Attached: Supplemental Declaration
of Tracy Grim